Remarks

Support for the Amendments

These amendments are being made to place the claims in better condition for allowance or appeal. No new matter is added, and additional search is not required. Support for "cytotoxic T-lymphocytes" in the amendment to Claim 68 can be found, *inter alia*, at page 1, lines 11-13, page 5, lines 15-16, page 21, lines 1-17 and similar language is found in claims 1 and 7. Support for "vectors which express said target epitope ..." in the amendments to Claim 68 and 70 can be found, *inter alia*, on page 50, lines 8-12, 21-23 and on page 51, Table 5. Support for "control signal" in the amendments to Claims 79, 80, 86, 87, and 89 can be found, *inter alia*, on page 25, lines 3-5 and on page 42, lines 19-23. These amendments do not change the scope of the claims in any way, and are made to more precisely claim what the Applicant regards as the invention. Accordingly, these amendments present no new matter. Entry of these amendments is respectfully requested.

Rejection of claims 68, 70, 79, and 92 under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 68, 70, 79, and 92 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time of filing. As applied to the claims as amended herein, Applicant respectfully traverse this rejection.

The Examiner states that "the 'specific T-lymphocytes' of Claim 68 have no clear support in the specification and claims as originally filed...," alleging that the specification does not support the claim. Paper No. 22, p. 2.

While not acquiescing to the Examiner's rejection, Applicant has amended Claim 68 to be drawn to "cytotoxic T-lymphocytes." Support for the amendment can be found throughout the specification, as indicated *supra*. Accordingly, withdrawal of this rejection is respectfully requested.

Applicant also notes that although the reference the Examiner cites, Janeway and Travers (1994), specifically teaches that "cytotoxic T cells ... are distinguished by the cell surface molecule CD8," it is known in the art that cytotoxic T lymphocytes (CTL) can have either CD8 or CD4 on their surface. Among numerous reports published between 1988 through 1996 is a report from Faber *et al.* (1995) describing reactive donor CD4+ as well as CD8+ CTL that were characterized after bone marrow transplantation between HLA identical siblings (abstract attached hereto as Exhibit A). Therefore, cytolytic CD4+ cells should be included as well as cytolytic CD8+ cells in the term "cytotoxic T-lymphocyte."

The Examiner states that "the term 'facilitating expression' of Claim 70 has no clear support in the specification and claims as originally filed...," alleging that the specification does not disclose the exact term. Paper No. 22, p. 3.

While not acquiescing to the Examiner's rejection, Applicant has amended Claims 68 and 70 to be drawn to "vectors which express said target epitope...." Support for the amendment can be found throughout the specification, as indicated *supra*. As indicated *infra*, the claims need not recite the specification verbatim, and those skilled in the art would

readily recognize that the inventor was in possession of the claimed invention at the time of filing. The amended language has precisely the same scope and meaning as the original language, however, the amendments are made to place the claims in better condition for allowance or appeal.

The written description requirement of 35 U.S.C. § 112 serves to ensure that the inventor had possession, as of the filing date, of the claimed subject matter. However, "how the specification accomplishes this is not material." *In re Wertheim*, 191 U.S.P.Q. 90, 96 (C.C.P.A. 1976). Further, "[i]f a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met." *In re Alton*, 37 U.S.P.Q. 2d 1578, 1584 (C.A.F.C. 1996).

The use of expression vectors, for example viral expression vectors, is well known in the art. As described in the specification on page 30 line 21 to page 31 line12, *inter alia*, viral vectors are commonly used to express particular proteins. In the present situation, the vaccinia vector claimed in the invention is clearly demonstrated to express a target peptide, ovalbumin, and by extension other target peptides, as described in the amended specification on page 50, lines 8-12, 21-23, and on page 51, Table 5. Based on the disclosure in the specification, one skilled in the art would readily recognize that the Applicant had possession of vectors expressing target epitopes according to the amended Claims 68 and 70. Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner states that "the term 'control region' of Claim 79 has no clear support in the specification and claims as originally filed...," alleging that the specification does not disclose the exact term. Paper No. 22, p. 3.

While not acquiescing to the Examiner's rejection, Applicant has amended Claims79 and dependent Claims 86, 87, and 89 to be drawn to a "control signal." Support for the amendment can be found throughout the specification, as indicated *supra*. The amended language has precisely the same scope and meaning as the original language. As previously discussed, the claims need not recite the specification verbatim, and those skilled in the art would readily recognize that the inventor was in possession of the claimed invention at the time of filing; however, the amendments are made to better to place the claims in better condition for allowance or appeal. Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner states that "the term 'counterpart' of claim 92 has no clear support in the specification and claims as originally filed...," alleging that the specification does not disclose the exact term. Paper No. 22, p. 3.

Examiners are instructed that in making a written description analysis:

> the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed. The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement.

M.P.E.P. § 2163.02. Therefore, the use of terminology in the claims that is clear to those skilled in the art need not be taken verbatim from the specification. In each of the examples

disclosed,*inter alia*, on page 1, lines 14-17 and page 14, lines 7-8, a comparison of tumor cells to the normal, non-tumorigenic cells from which the tumor cells were derived was described. Therefore, in claim 92, "non-tumorigenic counterpart cell" clearly indicates the normal cells as discussed in the examples given in support of the claim. As discussed *supra*, *in haec verba* is not necessary for the disclosure to satisfy the description requirement. Accordingly, withdrawal of this rejection is respectfully requested.

In view of these remarks, Applicant respectfully requests that the Examiner reconsider and withdraw all rejections under 35 U.S.C. § 112, first paragraph, as applied to the pending claims.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicant believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Version with markings to show changes made

68. (Once Amended) A method for selecting a nucleic acid molecule encoding a target epitope of [specific] cytotoxic T-lymphocytes, comprising:

(a) contacting host cells with cytotoxic T-lymphocytes specific for said target epitope under conditions wherein a host cell expressing said target epitope undergoes a lytic event upon contact with said T-lymphocytes; wherein said host cells comprise a library of heterologous nucleic acid molecules, at least one of said heterologous nucleic acid molecules encoding said target epitope, wherein said library is constructed in a vector [capable of facilitating expression of] which expresses said target epitope in said host cells, wherein said host cells express a defined MHC molecule, and wherein said cytotoxic T-lymphocytes are restricted for said MHC molecule; and

(b) recovering those host cells which have undergone a lytic event.

70. (Once Amended) The method of claim 68, further comprising:

(a) isolating said vector from those host cells which have undergone a lytic event;

(b) transferring said vector to a population of host cells, wherein said vector [is capable of facilitating expression of] expresses said target epitope in said host cells, and wherein said host cells express a defined MHC molecule;

(c) contacting said host cells with cytotoxic T-lymphocytes specific for said target epitope and restricted for said MHC molecule, under conditions wherein a host

cell expressing said target epitope will undergo a lytic event upon contact with said T-lymphocytes; and

(d) recovering those host cells which have undergone a lytic event.

79. (Once Amended) The method of claim 76, wherein said vector further comprises a transcriptional control [region] signal in operable association with said heterologous nucleic acid molecules, and wherein said transcriptional control [region] signal functions in a poxvirus.

80. (Once Amended) The method of claim 79, wherein said transcriptional control [region] signal comprises a promoter.

86. (Once Amended) The method of claim 79, wherein said transcriptional control [region] signal comprises a transcriptional termination region.

87. (Once Amended) The method of claim 79, wherein said vector further comprises a translational control [region] signal associated with said transcriptional control region.

89. (Once Amended) The method of claim 87, wherein said translational control [region] signal comprises a translation initiation codon operably linked to said heterologous nucleic acid molecules.